

REMARKS/ARGUMENTS

Original claim 1 has been amended as provided above while previous claims 2-16 have been represented as new claims 18-32, respectively. Support for the amendment to claim 1 and new claim 17 is provided in claim 1 as originally filed and in the specification at least at paragraphs 38 and 42. Applicants believe that claim 1 has not been narrowed, in part for the reasons provided below which explain how the amendments merely expressly recite the nature of the invention as intended and previously claimed.

Of claims 2-16, claims 13 and 16 (now claims 29 and 32) have been amended to be dependent from claim 1. Claims 18, 30, and 31 have been amended relative to previous claims 2, 14, and 15 to correct a grammatical informality without altering the scope of the claims. Claim 21 has been amended relative to previous claim 5 as supported by paragraph 28 of the instant application. Claim 25 has been amended relative to previous claim 9 to improve the grammatical correspondence with the language of claim 1 without narrowing the scope of the claim. Claims 29 and 32 have been amended relative to previous claims 13 and 16 to conform them to the language of amended claim 1. Support for all of the claim amendments is found throughout the specification and claims as originally filed.

Support for new claims 33-44 is also found throughout the specification and claims as originally filed. For example, support for claims 33-35 is found at least in ¶6, 17 and 48 of the instant specification; for claims 36-38, in at least ¶1 and 2 of the instant specification; for claim 39, in at least ¶34 of the instant specification; for claims 40-41, in at least ¶43 of the instant specification; for claims 42-43, in at least ¶16 and 34 of the instant specification; and for claim 44, in at least claim 1 as originally filed.

No new matter has been presented, and entry of the above amendment to the claims is respectfully requested.

Discussion of the invention

As an initial matter, Applicants believe that a description of the physical arrangement of the lungs and components thereof would be helpful in the understanding of the invention. As provided in the instant application, the instant invention is based upon the formulation and use of aerogel particulates that are able to deliver therapeutic agents to the bloodstream via the lung of a subject. The particulates are able to do this by reaching the alveoli/alveolar sacs of the lung, which are the final branches of the respiratory tree and act as the primary gas exchange units of the lung. Oxygen in air reaches the blood by diffusing through the alveolar epithelium, a thin interstitial space, and the capillary endothelium. Carbon dioxide in the blood follows the reverse course to reach the alveoli.

Movement of air from the outside of the lung to the alveoli/alveolar sacs can be generally described as follows: air enters via the bronchus/bronchi which becomes smaller passageways called the bronchioles. The bronchioles become terminal bronchioles which divides into two or more respiratory bronchioles, which have occasional alveolar sacs. The respiratory bronchioles further narrow to become respiratory units, each of which is a discrete group of alveoli arranged in alveolar sacs. As noted in paragraph 38 of the instant application, the air velocity approaches zero as the air reaches the alveoli.

Alveolar epithelial cells are of two types. Type I cells make up the thin alveolar epithelium and have long cytoplasmic extensions which spread out thinly along the alveolar walls. Type II cells are responsible for producing surfactant and are compact. Surfactant lines the alveoli and is a phospholipid which serves to differentially reduce surface tension at different volumes, contributing to alveolar stability.

The claims as originally filed encompassed aerogel particulates that deliver therapeutic agents to the blood by being "soluble in human pulmonary surfactant". As such, the particulates were of a density and size that permitted them to reach the alveoli where pulmonary surfactant is present. The claims as amended merely expressly recite this characteristic of the invention as claimed and so are not believed to be narrower in scope.

Rejections under 35 U.S.C. § 103(a)

Claims 1 and 5-7 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Unger (USP 6,403,056 B1). Applicants have carefully reviewed the instant rejection and traverse the rejection as failing to present a *prima facie* case of obviousness.

Unger fails to disclose or suggest aerogel particulates with “a density and particle size to permit them to reach the alveoli of a human subject’s lungs upon inhalation” as recited in amended claim 1. To the contrary, Ungar describes vesicles which are “characterized by the presence of one or more walls or membranes which form one or more internal voids.” (see column 4, lines 24-26). Such vesicles would have a density too great to avoid settling out of suspension in air before they would reach the alveoli of the human lung.

To the extent that the instant rejection is based upon the concept of “aerogel vesicles”, Applicants respectfully submit that Unger still fails to disclose or suggest particulates as encompassed by the instant claims. In the absence of such a teaching or suggestion, it is simply not possible for Unger to anticipate or render obvious the instant claims. Accordingly, Applicants respectfully submit that this rejection is misplaced with respect to the pending claims and so may be properly withdrawn.

Claims 2-4 and 8-16 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Unger (USP 6,403,056 B1) in light of Abbott et al. (USP 6,277,489). Applicants have carefully reviewed the instant rejection and traverse the rejection as failing to present a *prima facie* case of obviousness.

The deficiencies of Unger have been explained above. Abbott et al. is directed to solid supports that can be used for other molecules or “incorporated into an aerogel” (see abstract and column 4, lines 7-21). There is no disclosure of using such aerogels as particulates with “a density and particle size to permit them to reach the alveoli of a human subject’s lungs upon inhalation” as recited in the pending claims.

Given the deficiencies of both Unger and Abbott et al., it is simply not possible for Unger and Abbott et al. to render the instant claims obvious. Accordingly, Applicants

Appl. No. 09/982,544
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respectfully submit that this rejection is misplaced with respect to the pending claims and so may be properly withdrawn

Conclusion

Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is urged.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6151 .

Respectfully submitted,



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